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10/507,030	09/08/2004	Renate Bender	MERCK-2915	7689
23599 7590 04/14/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
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GERIDO, DWAN A				
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1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,030

Applicant(s)

BENDER ET AL.

Examiner

Dwan A. Gerido, Ph.D.

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. For claims 33-38, applicant claims a method of using the device of claim 1 without reciting steps for carrying out the claimed method. Thus it is unclear which method steps are claimed for chemical reactions, electrophoretic separations, isotachophoretic separations, and polymerase chain reactions. It is also unclear what method steps are involved in distributing and collecting a sample material as recited in claims 37 and 38.
4. Claim 1 recites the limitations "the fluid line connections" and "the electrical line connections" in lines 9 and 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-4, 6, 7, 9, 15, 17, 22-24, 26-29, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr et al., (US 6,319,476) and in further view of Sarrine et al., (US 5,516,402).

9. With regards to claims 1, 15, and 17, Schwalbe et al., teach a microcomponent connection system comprising a mounting bracket (accommodation device) and a plurality of line connections in which the line connections are pressed against one another by a lifting device (page 11 paragraphs 6 and 7, figures 10 and 11). Schwalbe et al., also teach the device in electrical and fluid connection with various embodiments of the invention (page 7 paragraph 4,

page 8 paragraph 6 line 2). Schwalbe et al., do not teach the fluid lines having an axially movable, spring mounted hollow ram.

Victor Jr. et al., teach a microfluidic connector wherein the fluid line connector has an axially movable, spring mounted hollow ram (column 4 lines 23-39, figure 4 #'s 22, 23). Victor Jr. et al., also teach a sealing ring around the aperture of the hollow ram (column 2 lines 50-54, column 4 lines 23-39, figure 4 #21). Victor Jr. et al., teach that it is advantageous to utilize a fluid line connector with a hollow ram as a means of providing a fluid tight seal with a low fluid dead volume. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Victor Jr. et al., to utilize a spring mounted hollow ram in order to provide a fluid tight seal with a low fluid dead volume as taught by Victor Jr. et al. Schwalbe et al., in view of Victor Jr. et al., do not teach a device comprising spring mounted electrical connections.

Sarrine et al., teach an electrophoresis device in which spring loaded contacts are used for electrical connections to electrodes (column 8 lines 51-60). The language regarding the electrical connections is sufficiently broad that it does not overcome the prior art as cited. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Victor Jr. et al., in further view of Sarrine et al., to utilize spring mounted electrical connections in order to provide an axially movable electrical input/output as taught by Sarrine et al.

10. With regards to claim 2, Schwalbe et al., teach a microcomponent pressed against the connection lines by means of a lifting device (page 11 paragraphs 6 and 7, figures 10 and 11).

11. With regards to claim 3, , Schwalbe et al., teach the line connections pressed against the microcomponent by a lifting device (page 11 paragraph 7 line 1, figure 10 #85).
12. With regards to claim 4, Schwalbe et al., teach a lifting device that is actuated manually by a lever (page 11 paragraph 7 lines 3-5).
13. With regards to claim 6, Schwalbe et al., teach the microsystem with a plate (connection block) and line connections passed through the plate (page 11 paragraph 6 lines 1 and 2, figures 10 and 11 #'s 84 and 85), wherein the microcomponent is pressed in the direction of the connection block by a lifting device (page 11 paragraph 7 lines 3-5, figure 10 #'s 84 and 85).
14. With regards to claim 7, Schwalbe et al., teach a system in which the microcomponent within an accommodation device is positioned by a reactor frame with the dimensions of the microreactor (page 11 paragraph 8 line 2).
15. With regards to claim 9, Schwalbe et al., teach a system wherein the orientation (coding) of the fluid and electric lines enables alignment of an accommodated microcomponent.
16. With regards to claims 18-21, Schwalbe et al., teach a microcomponent connection system comprising a mounting bracket (accommodation device) and a plurality of line connections in which the line connections are pressed against one another by a lifting device (page 11 paragraphs 6 and 7, figures 10 and 11 #'s 96 a-e). In addition, Schwable et al., teach various embodiments that include a range of control parameters including optical systems (page 9 paragraph 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in a manner that provides optical line connections in conjunction with the hollow ram in order to utilize the reactor with numerous

chemical reactions and a variety of detection systems as taught by Schwalbe et al. Regarding the hollow ram, see reference to Victor Jr. et al., supra.

17. With regards to claims 22 and 23, Victor Jr. et al., teach the hollow ram having a cone (figure 4 #22). Regarding the elastic material cited in claim 23, applicants do not list any specific materials or specific parameters concerning the elastic properties of the material used to make the hollow ram; therefore, the material as taught by Schwalbe et al., is being read on the claimed elastic material.

18. With regards to claim 24, the line connections as taught by Schwalbe et al., are located on plates that cover the top and bottom portions of the microcomponent. The device as taught by Schwalbe et al., reads on the instant claim in that the opposing connection (optical) lines would project over the channel section of the microcomponent on both sides (figures 10 and 11 #'s 96 a-e).

19. With regards to claim 26, Schwalbe et al., teach the device having a light source, but does not explicitly teach the light source opposite of an optical line connection.

20. With regards to claim 27, the line (optical) connections of Schwalbe et al., projects over a channel section of the microcomponent on both sides (figures 10 and 11 #'s 96 a-e).

21. With regards to claim 28, Schwalbe et al., teach a connection system wherein the lifting device has a support plate for the microcomponent (page 11 paragraphs 6 and 7, figures 10 and 11). Schwalbe et al., do not teach the support plate where the temperature of the plate is controlled by heating or cooling devices. Schwalbe et al do teach controlling the temperature of the microcomponent with a heat transfer fluid line (figure 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in a

manner in which the temperature of the support plate is controlled by heating mechanisms in order to control temperature of the the reaction by applying heat directly to the microcomponent.

22. With regards to claim 29, Schwalbe et al., teach the connection system with additional control elements (page 9 paragraph 4).

23. With regards to claim 31, Schwalbe et al., teach accommodating a plurality of microcomponents connected in series to the line connections (page 3 paragraph 6 lines 1 and 2, paragraph 7).

24. With regards to claim 32, Schwalbe et al., teach a microcomponent connection system comprising a plurality of line connections. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in a manner wherein the line connections are connected through connecting lines in order to ensure that the microcomponents arranged in the connection system are in fluid communication with each other (page 3 paragraph 5 line 1).

25. With regards to claim 33, Schwalbe et al., teach a microcomponent connection system for performing microfluid controlled chemical reactions (page 4 paragraph 3).

26. With regards to claim 37, Schwalbe et al., teach accommodating a plurality of microcomponents (page 3 paragraph 6 lines 1 and 2, paragraph 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., to distribute the sample material over the plurality of microcomponents in order to gain the advantage of performing reactions in parallel and increasing throughput.

27. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr. et al., (US 6,319,476) in view of Sarrine et al., (US 5,516,402) and in further view of Bergh et al., (US 6,737,026).

28. With regards to claim 5, Schwalbe et al., teach a microcomponent connection system in which the lifting device is actuated by a lever (page 11 paragraph 7 lines 3-5). Schwalbe et al., do not teach a system wherein the lifting device is actuated by a pneumatic cylinder, electrically driven scissor jack, or an electric spindle drive. Bergh et al., teach a microreactor where the catalyst wafer is brought into contact with a manifold controlled by a pneumatic device (column 72 lines 5-13). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Bergh et al., to gain the advantage of providing a mechanical lifting device in order to operate the system independently of the user.

29. With regards to claim 8, Schwalbe et al., teach a system wherein the connection block, frame, and lifting device forms a slot on one side through which the microcomponent is accommodated (figure 11 #76).

30. Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr et al., (US 6,319,476) and in view of Sarrine et al., (US 5,516,402) and in further view of Unno et al., (US 2003/0021725).

31. With regards to claim 10, Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., do not teach the microcomponent having a recess, nor do they teach the frame of the microcomponent connection system having a projection to match the recess.

Unno et al., teach a microfluidic device wherein the device has corresponding recesses and projections placed on the body (microcomponent) and nesting structure (microcomponent)

respectively. Unno et al., teach that it is advantageous to form corresponding recesses and projections as a means of providing an interface between two components. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., in further view of Unno et al., to utilize corresponding recesses and projections in order to form a microcomponent configured to interface with a specific microcomponent connexion system as taught by Unno et al.

32. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr et al., (US 6,319,476) and in view of Sarrine et al., (US 5,516,402) as applied to claim 18 above, and further in view of Corcoran et al., (US 2003/0180190).

33. With regards to claim 25, Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., teach a microcomponent connection system comprising a mounting bracket (accommodation device) and a plurality of line connections in which the line connections are pressed against one another by a lifting device (page 11 paragraphs 6 and 7, figures 10 and 11 #'s 96 a-e). Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., do not teach the microcomponent system with a reflection layer in the region of a channel section.

Corcoran et al., teach a microchamber with a light reflective coating in the chamber well (paragraph 0075). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Corcoran et al., to gain the advantage of measuring the optical properties of the reaction product(s) in order to determine the chemical nature of the product(s).

34. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr et al., (US 6,319,476) and in view of Sarrine et al., (US 5,516,402) as applied to claim 1 above, and further in view of Bostick et al., (US 4,263,406).

35. With regards to claim 30, Schwalbe et al., teach a microcomponent connection system comprising a mounting bracket (accommodation device) and a plurality of fluid line connections in which the line connections are pressed against one another by a lifting device (page 11 paragraphs 6 and 7, figures 10 and 11). Schwalbe et al., do not teach a frit arranged in the fluid line. Bostick et al., teach a microreactor with a frit located in a fluid line

Bostick et al., teach a microreactor with a frit located in a fluid line (column 8 lines 1-3). It is advantageous to utilize a frit in a fluid line as a means of filtering unwanted sample or particulates. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., in further view of Bostick et al., to utilize a frit in a fluid line in order to filter unwanted sample or particulates and prevent the unwanted material from interfering with the reactants, products, or the reaction.

36. Claims 34, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr et al., (US 6,319,476) and in view of Sarrine et al., (US 5,516,402) as applied to claim 1 above, and further in view of Andresen et al., (US 4,708,782).

37. With regards to claim 34, Schwalbe et al., teach a microcomponent connection system comprising a mounting bracket (accommodation device) and a plurality of fluid line connections in which the line connections are pressed against one another by a lifting device (page 11

paragraphs 6 and 7, figures 10 and 11). Schwalbe et al., do not teach a microcomponent connection system for electrophoretic separations and analysis.

Andresen et al., teach a capillary type electrophoresis device for electrophoretic separations and analysis (column 4 lines 40-48). It is advantageous to utilize electrophoretic separation and analysis as a means of separating charged particles based on size. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., in further view of Andresen et al., to utilize electrophoretic separation in order to determine the size distribution of charged reaction products.

38. With regards to claim 35, isotachophoretic separations are a type of electrophoretic separation therefore it would have been obvious to one of ordinary skill in the art to include utilize isotachophoretic separations to gain the advantage of separating charged reaction products.

39. With regards to claim 38, the device as taught by Andresen et al., performs chromatographic separations (column 4 lines 40-48).

40. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalbe et al., (WO 2001/089681) in view of Victor Jr. et al., (US 6,319,476) and in view of Sarrine et al., (US 5,516,402) as applied to claim 1 above, and further in view of Tso et al., (US 6,613,560).

41. With regards to claim 36, Schwalbe et al., teach a microcomponent connection system comprising a mounting bracket (accommodation device) and a plurality of line connections in which the line connections are pressed against one another by a lifting device (page 11

paragraphs 6 and 7, figures 10 and 11). Schwalbe et al., do not teach a microcomponent connection capable of performing polymerase chain reactions (PCR).

Tso et al., teach a microchamber/microreactor for performing PCR (column 5 lines 49-55, claim 13). Tso et al., teach that it is advantageous to utilize a microchamber/microreactor as a means of performing PCR with microquantities of sample fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schwalbe et al., in view of Victor Jr. et al., in view of Sarrine et al., in further view of Tso et al., to utilize the microcomponent for PCR in order to perform PCR reactions with small sample volumes as taught by Tso et al.

Response to Arguments

42. Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

43. Applicant has amended the independent claims to include the limitations of fluid line connections, hollow rams, and electrical line connections. Applicant has also cancelled claims 11-14, and 16. Claims 33-38 are rejected under 35 U.S.C. 112 for being unclear as to the subject matter recited in the claims. As presented, claims 33-38 do not recite method steps therefore; it is unclear as to how the claimed method is performed with the claimed device. Claim 1 is also rejected under 35 U.S.C. 112 for lacking antecedent basis for the limitations 'the fluid line connections' and 'the electrical line connections'. Regarding the art rejections listed above, reference to Victor Jr. et al., is relied upon for teaching a axially movable, spring mounted hollow ram with a sealing ring whereas reference to Sarrine et al., is relied upon for teaching spring mounted electrical contacts. It is the examiners position that the prior art cited above

meets the claim limitations in that the claims are sufficiently broad so as to read on the above references. Specifically, applicant does not describe the manner in which the fluid line connections, hollow ram, and electrical line connections are connected or arranged within the device thus the arrangements of the prior art read on the limitations presented in claims 1-38.

Conclusion

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

DAG